New Zealand Datasheet

1 PRODUCT NAME
BENZAC® AC Wash

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Benzoyl Peroxide gel 50 mg/g

3 PHARMACEUTICAL FORM
BENZAC AC Wash contains benzoyl peroxide 50mg/g in a white to off-white gel base

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
For the treatment of mild to moderate acne vulgaris.

4.2 Dosage and method of administration
Unless otherwise prescribed, the preparation should be applied once or twice daily to cover the affected skin. Wet the area to be treated. Apply the preparation to the hands and wash the affected areas with the gel. Contact time with the skin should be 30 seconds and not exceeding 5 minutes, followed by a thorough rinsing with water and drying.

4.3 Contraindications
BENZAC AC Wash is contraindicated in patients with a history of hypersensitivity to any of its ingredients.

4.4 Special warnings and precautions for use
For external use only. In normal use a mild burning sensation will probably be felt on first application and a moderate reddening and peeling of the skin will occur within a few days. During the first weeks of treatment a sudden increase in peeling will occur in most patients, this is not harmful and will normally subside within a day or two if treatment is temporarily discontinued. If severe irritation occurs, patients should be directed to use the medication less frequently, to temporarily discontinue use or to discontinue use altogether.

Benzoyl peroxide may cause swelling and blistering of the skin, if any of these symptoms occur, medication has to be discontinued.

BENZAC AC 5% Wash should not come into contact with eyes, mouth, angles of the nose or mucous membranes. If the preparation enters the eye wash thoroughly with water. Caution should be exercised when applying BENZAC AC Wash to the neck and other sensitive areas.

The repeated exposure to sunlight or UV irradiation should be avoided.

Contact with any coloured material including hair and dyed fabrics may result in bleaching or discolouration.

Due to the risk of sensitization, benzoyl peroxide gel should not be applied on damaged skin.

4.5 Interaction with other medicines and other forms of interaction
There are no known interactions with other medications which might be used cutaneously and concurrently with BENZAC AC Wash however drugs with desquamative, irritant and

drying effects should not be used concurrently with BENZAC AC Wash.

4.6 Fertility, Pregnancy and lactation

There is no safety concern relating to the effects of cutaneously applied benzoyl peroxide on reproductive function, fertility, teratogenicity, embryotoxicity, or peri- and post- natal development from animal data.

In widespread clinical use for the cutaneous treatment of acne vulgaris, at concentrations up to 10% w/w for several decades, benzoyl peroxide has never been associated with such effects in humans. Benzoyl peroxide gel should only be used by a pregnant woman if clearly needed.

It is not known whether benzoyl peroxide is excreted in animal or human milk. Because many drugs are excreted in human milk, caution should be taken when BENZAC AC 5% Wash is administered to a breastfeedingwoman. In this event, the preparation should not be applied on the chest to avoid accidental transfer to the infant.

4.7 Effects on ability to drive and use machines

BENZAC AC Wash has no or negligible influence on the ability to drive and use machines

4.8 Undesirable effects

The adverse reactions resulting from clinical trials are all skin disorders. They are reversible when treatment is reduced in frequency or discontinued.

The following categories are used to indicate the frequency of occurrence of adverse effects:

Very common (≥1/10) Common
(≥1/100 to <1/10) Uncommon
(≥ 1/1,000 to <1/100) Rare
(≥1/10,000 to <1/1,000) Very
rare (<1/10,000)
Unknown (Frequency not assessable based on the available data).

They are presented in the table below:

Skin and subcutaneous tissue disorders	Very common (≥1/10)	Dry skin Erythema Skin exfoliation (peeling) Skin Burning sensation
	Common (≥1/100 to <1/10)	Pruritus Pain of skin (pain, stinging) Skin irritation (irritant contact dermatitis)
	Uncommon (≥ 1/1,000 to <1/100)	Allergic contact dermatitis

Swelling face and allergic reactions, including application site hypersensitivity and anaphylaxis (unknown frequency) have been reported during post-marketing surveillance.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It

allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

BENZAC AC Wash is for cutaneous use only. If the medication is applied excessively, no more rapid or better results will be obtained and severe irritation might develop. In this event treatment must be discontinued and appropriate symptomatic therapy should be instituted.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-acne preparations for topical use, ATC Code: D10AE01

Benzoyl peroxide has been shown to have potent broad spectrum antimicrobial activity, particularly against *Proprionibacterium acnes* which is normally present in affected hair follicles. In addition benzoyl peroxide has demonstrated exfoliative and comedolytic activities both of which are beneficial in the treatment of acne.

5.2 Pharmacokinetic properties

The percutaneous penetration of benzoyl peroxide in rat, rabbit, monkey and man is low. The majority of the penetrated benzoyl peroxide is converted into benzoic acid which after absorption into the systemic circulation is rapidly eliminated by the kidney. There is no evidence of any tissue accumulation. There is no evidence that cutaneous application of the proposed clinical doses of BENZAC AC Wash should be associated with any systemic adverse reactions in humans.

5.3 Preclinical safety data

In animal studies by the cutaneous route, benzoyl peroxide is associated with a minimal to moderate skin irritation potential including erythema and oedema. Phototoxic and photoallergic reactions have been reported for benzoyl peroxide therapy.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acrylates copolymer, glycerol, carbomer 940, sodium C14-C16 olefin sulfonate, sodium hydroxide and purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Plastic bottles of 200mL and 20ml

6.6 Special precautions for disposal

Not applicable.

7 MEDICINE SCHEDULE

General Sale Medicine

8 SPONSOR

Sponsor and distributor in New Zealand
Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland
New Zealand
Ph (09) 918 5100
Fax (09) 918 5101

For:
Galderma Australia Pty Ltd
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9 DATE OF FIRST APPROVAL

3 July 1995

10 DATE OF REVISION OF THE TEXT

19 November 2018

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
8.0	Correction of sponsor details